

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**A PROCESS OF MANUFACTURE OF NOVEL DRUG DELIVERY SYSTEM:
MULTILAYER TABLET COMPOSITION OF THIAZOLIDINEDIONE AND
BIGUANIDES**

the specification of which was filed on December 16, 2004 as Application No. 10/518,044.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by an amendment, if any, specifically referred to herein.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

☐ no foreign applications have been filed

☒ foreign application(s) have been filed as follows:

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Application Number	Country	Date of Filing	Priority Claimed Under 35 USC 119
533/MUM/2002	INDIA	June 17, 2002	<u> x </u> Yes No <u> </u>
			<u> </u> Yes No <u> </u>
			<u> </u> Yes No <u> </u>

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Application Number	Country	Date of Filing

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

☒ no U.S. provisional applications have been filed.

☐ U.S. provisional application(s) have been filed as follows:

Application Number	Date of Filing	Priority Claimed Under 35 USC 119
		<u> </u> Yes No <u> </u>
		<u> </u> Yes No <u> </u>
		<u> </u> Yes No <u> </u>

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the

first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56 which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

- ☐ no U.S./PCT applications have been filed.
- ☒ U.S./PCT application(s) have been filed as follows:

Application Number	Date of Filing	Status (Patented/Pending/Abandoned)
PCT/IN02/00207	October 14, 2002	Published

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint:

All practitioners at Customer Number 25227

all of **Morrison & Foerster LLP**, , jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

Please mail all correspondence to Raj S. Davé , whose address is:

Morrison & Foerster LLP
2000 Pennsylvania Ave., NW
Washington, DC 20006-1888

Please direct telephone calls to: Raj S. Dave' at (202) 887-1547.

Please direct facsimiles to: (703) 760-7777

1-00

Full name of sole or first inventor Amit Krishna ANTARKAR	
Sole or first inventor's signature <i>Amit Antarkar</i>	Date 10/AUGUST/2005
Residence Nagpur, India <i>INX</i>	
Citizens India	
Mailing Address House No. C/4 Rani Laxmi Nagar Nagpur-440 022 INDIA	

2-00

Full name of second inventor, if any Rajendra Ghanshamlal LALA	
Second inventor's signature <i>Rajendra</i>	Date 10/AUGUST/2005
Residence Mumbai, India <i>INX</i>	
Citizens India	
Mailing Address House No. 100 Guru Cottage Inlaks Hospital Road, Chembur Mumbai, Maharashtra-400 074; INDIA	

3-00

Full name of third inventor, if any Nirav Mahendra KAMDAR	
Third inventor's signature <i>Nirav M. Kamdar</i>	Date 10/AUGUST/2005
Residence Mumbai, India <i>INX</i>	
Citizens India	
Mailing Address Wing A-1, Flat No. 201 Tara Tower Co-operative Housing Society Patil Paradise Complex Tambe Nagar; Sarojini Naidu Road; Mulund (West) Mumbai-400 080; INDIA	

Rec'd PCT/PTO 17 AUG 2005

Rec'd PCT/PTO 17 SEP 2005
Attorney Docket No.: 578832000100
10518044

4-00

Full name of fourth inventor, if any Parag Narayan GADKARI	
Fourth inventor's signature <i>[Signature]</i>	Date 10/AUGUST/2005
Residence Thane (west), India <i>INX</i>	
Citizenship India	
Mailing Address 23/703 Anant, Vasant Vihar Pokhran Road No. 2 Thane (west)-400 607 INDIA	

5-00

Full name of fifth inventor, if any Maya Janak SHAH	
Fifth inventor's signature <i>[Signature]</i>	Date 10/AUGUST/2005
Residence Mumbai, India <i>INX</i>	
Citizenship India	
Mailing Address Saujanya, 3rd N. S. Road Vallabhnagar Society Vile Parle (West) Mumbai-400 056; INDIA	

6-00

Full name of sixth inventor, if any Janak Ramanlal SHAH	
Sixth inventor's signature <i>[Signature]</i>	Date 10/AUGUST/2005
Residence Mumbai, India <i>INX</i>	
Citizenship India	
Mailing Address Saujanya, 3rd N. S. Road Vallabhnagar Society Vile Parle (West) Mumbai-400 056; INDIA	

ASSIGNMENT

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby assign(s), transfer(s) and set(s) over to:

**Themis Laboratories Private Limited
Unit No. S-4, Khira Industrial Estate
B.M. Bhargava Road
Santacruz (West)
Mumbai 400 054, State of Maharashtra
India**

(hereinafter designated as the "ASSIGNEE"), its successors and assigns, the entire right, title, and interest for the United States in the invention, and all applications for patent and any Letters Patent which may be granted therefor, including said application, and all United States Letters Patent which may be granted thereof, and all divisions, reissues, continuations and extensions thereof, the said interest being the entire ownership of said Letters Patent when granted to be held by said ASSIGNEE, its successors, assigns or their legal representatives, to the full end of the term for which said Letters Patent may be granted, as fully and entirely as the same would have been and enjoyed by Assignor(s) if this assignment had not been made, the application being known by the title:

**A PROCESS OF MANUFACTURE OF NOVEL DRUG DELIVERY SYSTEM:
MULTILAYER TABLET COMPOSITION OF THIAZOLIDINEDIONE AND
BIGUANIDES**

Attorney Docket No.: 57883-20001.00

for which the undersigned has/have executed an application for patent in the United States of America on the same day herewith. Where this instrument is not filed concurrently with the application, the following identifying information may be added after execution:

Serial No.: 10/518,044

Filing Date: December 16, 2004

1. The undersigned hereby agree(s) to sign and execute any further documents and instruments which may be necessary, lawful and proper in the prosecution of said above-named application or in the preparation and prosecution of any continuing, continuation-in-part, substitute, divisional, renewal, reexamination or reissue application or in any amendments, extension of interference proceedings, or otherwise to secure the title thereto to the ASSIGNEE.

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2. The undersigned agree(s) to execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property of similar agreements.

3. The undersigned agree(s) to perform all affirmative acts which may be necessary to obtain a grant of a valid United States patent to the ASSIGNEE.

4. The undersigned hereby authorize(s) and request(s) the Commissioner of Patents in the United States to issue any and all Letters Patent resulting from said application or any division or divisions or continuing applications thereof to the said ASSIGNEE.

5. The undersigned hereby grant(s) to the firm of Morrison & Foerster LLP the power to insert on this assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

IN WITNESS WHEREBY, executed by the undersigned on the date(s) opposite the undersigned name(s).

10 AUGUST 2005

Date

Amit Antarkar

Typed Name: Amit Krishna ANTARKAR

State of MAHARASHTRA)
) SS.
County of INDIA)

Subscribed and sworn to (or affirmed) before me this 10th day of

AUGUST (month), 2005 (year) by

Sangeeta Amalesh KARLE (name and address of signer).

25, Om Aditya Society, Ganeshwadi, Panchpakhadi,

Thane (West) – 400 602, Maharashtra, India

S. Karle

Signature of Witness

Subscribed and sworn to (or affirmed) before me this 10th day of

AUGUST (month), 2005 (year) by

Milind Vinayak SATHE (name and address of signer)

B-309, New Akshay Apartments CHS, Captain V. Gore Road,

Vile Parle (E) Mumbai – 400057, Maharashtra, India

M. Sathe

Signature of Witness

Attny. Docket No.: 578832000100


Page 2 of 7

Rec'd PCT/PTO 17 AUG 2005

~~Rec'd PCT/PTO~~ ~~17 SEP 2005~~ *C. D. S.*

10 AUGUST 2005

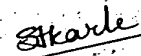
Date


Typed Name: Rajendra Ghanshamlal LALA

State of MAHARASHTRA)
) SS.
County of INDIA)

Subscribed and sworn to (or affirmed) before me this 10th day of AUGUST (month),
2005 (year) by

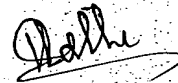
Sangeeta Amalesh KARLE (name and address of signer).
25, Om Aditya Society, Ganeshwadi, Panchpakhadi,
Thane (West) – 400 602, Maharashtra, India



Signature of Witness

Subscribed and sworn to (or affirmed) before me this 10th day of AUGUST (month),
2005 (year) by

Milind Vinayak SATHE (name and address of signer)
B-309, New Akshay Apartments CHS, Captain V. Gore Road,
Vile Parle (E) Mumbai – 400057, Maharashtra, India



Signature of Witness

10 AUGUST 2005

Date

Nirav M. Kamdar

Typed Name: Nirav Mahendra KAMDAR

State of MAHARASHTRA)

) SS.

County of INDIA)

Subscribed and sworn to (or affirmed) before me this 10th day of

AUGUST (month), 2005 (year) by

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Thane (West) – 400 602, Maharashtra, India

S. Karle

Signature of Witness

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Milind Sathe

Signature of Witness

Rec'd PCT/PTO 17 AUG 2005

~~Rec'd PCT/PTO 17 SEP 2005~~

10 AUGUST 2005

Date

ps n
Typed Name: Parag Narayan GADKARI

State of MAHARASHTRA)
) SS.
County of INDIA)

Subscribed and sworn to (or affirmed) before me this 10th day of

AUGUST (month), 2005 (year) by

Sangeeta Amalesh KARLE (name and address of signer).

25, Om Aditya Society, Ganeshwadi, Panchpakhadi,

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Skarle

Signature of Witness

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Sathe

Signature of Witness

Attny. Docket No.: 578832000100

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Rec'd PCT/PTO 17 AUG 2005

~~REC'D PCT/PTO 17 SEP 2005~~
COW

10 AUGUST 2005

Date

MASHAW

Typed Name: Maya Janak SHAH

State of MAHARASHTRA)

) SS.

County of INDIA)

Subscribed and sworn to (or affirmed) before me this 10th day of

AUGUST (month), 2005 (year) by

Sangeeta Amalesh KARLE (name and address of signer).

25, Om Aditya Society, Ganeshwadi, Panchpakhadi,

Thane (West) – 400 602, Maharashtra, India

Skarle

Signature of Witness

Subscribed and sworn to (or affirmed) before me this 10th day of

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Milind Vinayak SATHE (name and address of signer)

B-309, New Akshay Apartments CHS, Captain V. Gore Road,

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Sathe

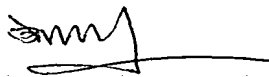
Signature of Witness

Attny. Docket No.: 578832000100

Page 6 of 7

10 AUGUST 2005

Date



Typed Name: Janak Ramanlal SHAH

State of MAHARASHTRA)

) SS.

County of INDIA)

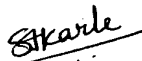
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Signature of Witness